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CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			EXAMINER SZMAL, BRIAN SCOTT	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/762,978
Filing Date: January 22, 2004
Appellant(s): HUNG ET AL.

Theodore Allen
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 22, 2007 and September 27, 2007
appealing from the Office action mailed April 3, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Hou et al "A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge" Radiology, vol195, May 1995, pp.568-569

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 90-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cecchi (5,843,023) in view of Hou et al (A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge).

Cecchi discloses an aspiration needle with a side port and further disclose: a manifold hub (17) in fluid communication with the cannula (13), the manifold hub (17) comprising a distal end having a first port (29) for infusing fluids into the hub (17) and a second port (16) for collecting fluid from within the hub (17); infusing a lavage fluid through the first port (29) and into the hub (17) (See Figures 1 and 2; and Column 5, lines 21-24); infusing lavage fluid from the hub (17) into the target site through the internal lumen (30) of the cannula (13) (See Figures 1 and 2; and Column 5, lines 21-24); withdrawing the lavage fluid and substances borne by the lavage fluid from the target site through the lumen (30) of the cannula (13) and into the hub (17); delivering

the lavage fluid into a collection device (26) through the second port (16) of the hub (17) (See Column 3, lines 9-14; and Column 5, lines 21-24); infusing the lavage fluid includes the step of applying a positive infusion pressure within the internal lumen (30) (See Column 3, lines 11-14; and Column 5, lines 22-24); the positive pressure is applied by a syringe (See Column 5, lines 22-24; the injection of saline implies the use of a device that connects to Luer port (24) and utilizes a positive pressure, such as a syringe); infusing the lavage fluid includes applying a positive pressure within the hub (17) (See Column 5, lines 22-24); withdrawing the lavage fluid and substances includes applying negative pressure within the internal lumen (30) (See Column 5, lines 22-23 and 46-47); the negative pressure is applied by a collection device, which is a syringe (See Column 5, lines 46-47); and withdrawing the lavage fluid and substances includes applying a negative pressure within the hub (17) (See Column 2, lines 62-64; the vacuum source creates a vacuum which is then transmitted to the hub and then to the internal lumen of the cannula in order to aspirate the sample).

Cecchi however fail to disclose inserting a distal end of a catheter through the ductal orifice and into a distal lumen of a duct or ductal network; the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct.

Hou et al disclose a method and means for placing a lavage fluid within a breast duct and receiving fluid from within the duct, and further disclose inserting a distal end of a catheter through the ductal orifice and into a distal lumen of a duct or ductal

network; and the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct. See Paragraph 4, under Materials and Methods, page 568, lines 1-7 and 12-17.

Since both Cecchi and Hou et al disclose means for infusing a lavage fluid and aspirating the lavage fluid and biological material from a target site, it would have been obvious to one of ordinary skill in the art to modify the method of Cecchi to utilize the device for lavaging a breast duct, as per the teachings of Hou et al, since it would provide a means of utilizing a first syringe for creating a vacuum and aspirating a fluid sample from the biopsy site and a second syringe for providing a lavage fluid to the biopsy site.

9(a) Grounds of Rejection Not on Review

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 90-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-65 and 68 of U.S. Patent No. 6,689,070 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the current application and the issued patent both disclose a method for lavaging a human breast duct, including essentially the same structural elements and method steps. While the issued patent broadly discloses the use of a catheter with an internal lumen, the current application discloses all of the structural elements of the catheter. One of ordinary skill in the art would be able to determine a catheter would inherently have a proximal end and a distal end and have an internal lumen with a distal opening for receiving and/or delivering a fluid into the body. Furthermore, the issued patent broadly discloses an infusion device and a collection device, while the current claims disclose a syringe for infusing a fluid and a syringe for collecting the fluid. One of ordinary skill in the art would be able to determine that a syringe is a type of a device that acts as both an infusion device as well as an aspiration device, because the withdrawal of the syringe plunger creates a vacuum for removing fluids from the body, while the advancement of the plunger creates a positive pressure within the syringe to inject fluids into the body. Since the claims of the issued patent broadly disclose the limitations of the current claims of the application, the current claims are not patentably distinct from the issued claims.

(10) Response to Argument

The Applicants argue that Cecchi fails to disclose the use of a manifold hub, and goes on to argue element (17), a "T-connector", in Cecchi is not a manifold hub. The Examiner respectfully disagrees. A manifold hub is nothing more than a means of uniting various elements (in the instant case, lumens) and connecting them at a single point. Element (17) in Cecchi clearly unites various lumens (32, 33 and the outlet at 14) and connects them at a single point (denoted at 18). The Applicants further argue that a manifold hub inherently suggests a space where fluids can be mixed and/or collected, and Cecchi fails to disclose such a space; this space is shown in Cecchi within the lumen between element (14) and (21) in Figure 2. The Applicants also go on to further argue "T-connector" (17) is not in fluid communication with cannula (13). One of ordinary skill in the art would be able to determine from the figures of Cecchi, that in order for the "T-connector" (17) to be able to irrigate and aspirate fluids from the collection site, the lumens of the "T-connector" (17) would have to be in fluid communication with the cannula (13). The Applicants further argue that Cecchi fails to teach or suggest the withdrawal of fluid through the cannula (13) and into the hub (17). During aspiration, fluid travels proximally through the cannula (13), through the "T-connector", and ultimately into vial (26). One of ordinary skill in the art would be able to determine, based on the direction of the fluid flow during aspiration, the fluid is withdrawn into the hub or "T-connector" (17). Therefore Cecchi teaches the use of a manifold hub.

The Applicants also argue neither Cecchi nor Hou et al teach or suggest a method for the collection of breast duct cells because Cecchi discloses a means for lavaging an oocyte from an ovary, and Hou et al discloses the placement of a radiopaque dye within the breast duct for imaging the breast duct of the patient. While Cecchi discloses the means for obtaining an oocyte from the ovary, the means comprises a lumen for insertion into the body of the patient, an irrigation source and a means for aspirating cells from the body connected via a manifold hub. Hou et al discloses a catheter comprising a lumen for insertion into the breast duct to infuse the breast duct with a substance. One of ordinary skill in the art would have been able to modify the means of Cecchi to include the use of a catheter distal tip for inserting the device into the breast duct of a patient, as taught by Hou et al. Furthermore, one of ordinary skill in the art would have been able to utilize the catheter of Hou et al to aspirate a fluid from the breast duct, since the catheter is used for applying a fluid to the breast duct; the lumen of such a catheter can be used for either irrigating or aspirating or both irrigating and aspirating.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Cecchi clearly

teaches the use of a means of lavaging an organ (ovary) to obtain cells (oocytes). Hou et al teach a system that is similar to Cecchi, but is used to lavage a breast duct. One of ordinary skill in the art would have been able to utilize the device of Cecchi as modified by Hou et al to lavage a breast duct, as currently claimed.


In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(11) Related Proceeding(s) Appendix


No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Brian Szmal 

Conferees:

Max Hindenburg 

Tom Barrett 